K133411

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is K133411

SUBMITTER
Alere Scarborough, Inc.
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Establishment Registration Number: 1221359

DEC 05 2013

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DATE PREPARED

TRADE NAME
Alere BinaxNOW® Influenza A & B Card

COMMON NAME
Not Applicable

CLASSIFICATION NAME
Influenza virus serological reagents (per 21 CFR 866.3330)

CLASSIFICATION
Class I

PRODUCT CODE
GNX

PANEL
Microbiology

PREDICATE DEVICE
Alere BinaxNOW® Influenza A & B Card, K092223

DEVICE DESCRIPTION
The Alere BinaxNOW® Influenza A & B Card is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to detect influenza type A and B nucleoprotein antigens in respiratory specimens. These antibodies and a control antibody are immobilized onto a membrane support as three distinct lines and combined with other reagents/pads to construct a test strip. This test strip is mounted inside a cardboard, book-shaped hinged test card.

Swab specimens require a sample preparation step, in which the sample is eluted off the swab into elution solution, saline or transport media. Nasal wash/aspirate samples require no preparation. Sample is added to

the top of the test strip and the test card is closed. Test results are interpreted at 15 minutes based on the presence or absence of pink-to-purple colored Sample Lines. The blue Control Line turns pink in a valid assay.

INTENDED USE

The Alere BinaxNOW® Influenza A & B Card is an *in vitro* immunochromatographic assay for the qualitative detection of influenza A and B nucleoprotein antigens in nasopharyngeal (NP) swab, nasal swab, and nasal wash/aspirate specimens. It is intended to aid in the rapid differential diagnosis of influenza A and B viral infections. Negative test results are presumptive and should be confirmed by cell culture or an FDA-cleared influenza A and B molecular assay. Negative test results do not preclude influenza viral infection and should not be used as the sole basis for treatment or other patient management decisions.

Caution: *Assay sensitivity for nasal wash/aspirate samples was determined primarily using archived specimens. Users may wish to establish the sensitivity of these specimens on fresh samples.*

COMPARISON TO THE PREDICATE

The Alere BinaxNOW® Influenza A & B Card, under consideration in this special 510(k) filing is exactly the same test as the currently 510(k) cleared Alere BinaxNOW® Influenza A & B Card, there have been no modifications to the test; the fundamental scientific technology of the test has not been altered. Both use lateral flow immunochromatographic technology. Both tests are rapid immunoassays that employ specific antibodies immobilized onto solid phases to capture and visualize influenza nucleoprotein antigens.

PERFORMANCE SUMMARY

The clinical performance of the Alere BinaxNOW® Influenza A & B Card was established in multi-center, prospective, clinical studies conducted at a central testing laboratory outside the US during the 2004 respiratory season and at three US trial sites during the 2005-2006 respiratory season. Additional performance testing was conducted on retrospective frozen clinical samples collected from symptomatic patients at multiple physician offices, clinics and hospitals located in the Southern, Northeastern and Midwestern regions of the United States and from one hospital in Sweden.

Clinical Studies:

Alere BinaxNOW® Influenza A & B Card Performance vs. Cell Culture / DFA – Prospective Study

A total of 846 prospective specimens collected from children (less than 18 years of age) and adults (18 years or older) were evaluated in the Alere BinaxNOW® Influenza A & B Card and compared to culture/DFA. Evaluated specimens include nasopharyngeal and nasal swabs collected from patients presenting with influenza-like symptoms. Forty-four percent (44%) of the population tested was male, 56% female, 54% pediatric (< 18 years), and 46% adult (≥ 18 years). No differences in test performance were observed based on patient age or gender. A/H3 and A/H1 were the predominant influenza subtypes observed during this time.

Alere BinaxNOW® Influenza A & B Card performance by sample type versus cell culture / DFA, including 95% confidence intervals, is listed below.

Alere BinaxNOW® Influenza A & B Card Performance vs. Cell Culture/DFA for Detection of Flu A

Test Sensitivity				
Sample	**+/+**	**-/+**	**% Sens**	**95% CI**
NP Swab	53	16	77%	65-86%
Nasal Swab	85	17	83%	74-90%
Overall	138	33	81%	74-86%

Test Specificity				
Sample	**-/-**	**+/-**	**% Spec**	**95% CI**
NP Swab	278	3	99%	97-100%
Nasal Swab	378	16	96%	93-96%
Overall	656	19	97%	96-98%

Alere BinaxNOW® Influenza A & B Card Performance vs. Cell Culture/DFA for Detection of Flu B

Test Sensitivity				
Sample	**+/+**	**-/+**	**% Sens**	**95% CI**
NP Swab	2	2	50%	9-91%
Nasal Swab	9	4	69%	39-90%
Overall	11	6	65%	39-85%

Test Specificity				
Sample	**-/-**	**+/-**	**% Spec**	**95% CI**
NP Swab	346	0	100%	99-100%
Nasal Swab	481	2	100%	98-100%
Overall	827	2	100%	99-100%

Alere BinaxNOW® Influenza A & B Card Performance vs. Cell Culture / DFA – Retrospective Study

A total of 293 retrospective frozen clinical samples were evaluated in the BinaxNOW® Influenza A & B Test and compared to culture/DFA. All clinical samples were collected from symptomatic patients at multiple physician offices, clinics and hospitals located in the Southern, Northeastern and Midwestern regions of the United States and from one hospital in Sweden. Fifty-three percent (53%) of the population tested was male, 47% female, 62% pediatric (<18 years) and 38% adult (≥ 18 years). Nasal wash/aspirate specimens comprised approximately 61% of the samples tested, while NP swabs represented 39%. No differences in test performance were observed based on patient age and gender or based on sample type tested.

Alere BinaxNOW® Influenza A & B Card performance by sample type versus cell culture / DFA, including 95% confidence intervals, is listed below.

Alere BinaxNOW® Influenza A & B Card Performance vs. Cell Culture/DFA for Detection of Flu A

Test Sensitivity				
Sample	**+/+**	**-/+**	**% Sens**	**95% CI**
NP Swab	19	8	70%	50-86%
Wash/Aspirate	51	6	89%	78-96%
Overall	70	14	83%	73-90%

Test Specificity				
Sample	**-/-**	**+/-**	**% Spec**	**95% CI**
NP Swab	77	9	90%	81-95%
Wash/Aspirate	117	6	95%	89-98%
Overall	194	15	93%	88-96%

Alere BinaxNOW® Influenza A & B Card Performance vs. Cell Culture/DFA for Detection of Flu B

Test Sensitivity				
Sample	**+/+**	**-/+**	**% Sens**	**95% CI**
NP Swab	0	0	N/A	N/A
Wash/Aspirate	8	7	53%	27-78%
Overall	8	7	53%	27-78%

Test Specificity				
Sample	**-/-**	**+/-**	**% Spec**	**95% CI**
NP Swab	111	2	98%	93-100%
Wash/Aspirate	155	10	94%	89-97%
Overall	266	12	96%	92-98%

Analytical Sensitivity:
The Alere BinaxNOW® Influenza A & B Card limit of detection (LOD), defined as the concentration of influenza virus that produces positive Alere BinaxNOW® Influenza A & B Card results approximately 95% of the time, was identified by evaluating different concentrations of inactivated Flu A/Beijing and inactivated Flu B/Harbin in the Alere BinaxNOW® Influenza A & B Card.

Twelve different operators each interpreted two cards run at each concentration for a total of 24 determinations per level. The following results identify a concentration of 1.03×10^2 ng/ml as the LOD for Flu A/Beijing and 6.05×10^1 ng/ml for Flu B/Harbin.

Flu A/Beijing		
Concentration (ng/ml)	**# Detected**	**% Detected**
1.03×10^2 (LOD)	23/24	96
5.60×10^1 (Cutoff)	*	50
3.27×10^1 (High Neg)	4/24	17
True Negative	0/24	0

Flu B/Harbin		
Concentration (ng/ml)	**# Detected**	**% Detected**
6.05×10^1 (LOD)	23/24	96
2.42×10^1 (Cutoff)	11/24	46
1.51×10^1 (High Neg)	6/24	25
True Negative	0/24	0

**Linear regression was used to calculate a line equation, which was then used to project the cutoff concentration of Flu A/Beijing.*

Analytical Reactivity:
The influenza A and B strains listed tested positive in the Alere BinaxNOW® Influenza A & B Card at concentrations specified. Although the specific influenza strains causing infection in humans can vary from year to year, all contain the conserved nucleoproteins targeted by the Alere BinaxNOW® Influenza A & B Card.[2] Performance characteristics of the Alere BinaxNOW® Influenza A & B Card for detecting influenza A virus from human specimens was established when H1 and H3 subtypes were prevalent. Performance characteristics of the test when other influenza A virus subtypes are emerging as human pathogens have not been established.

Influenza Strain	ATCC #	Concentration
Flu A/WS/33 (H1N1)	VR-825	10^2-10^6 $CEID_{50}$/ml
Flu A/NWS/33 (H1N1)	VR-219	10^2-10^6 $CEID_{50}$/ml
Flu A/Hong Kong/8/68 (H3N2)	VR-544	10^2-10^6 $CEID_{50}$/ml
Flu A/Aichi/2/68 (H3N2)	VR-547	10^2-10^6 $CEID_{50}$/ml
Flu A/New Jersey /8/76 (Hsw1N1)	VR-897	10^2-10^6 $CEID_{50}$/ml
Flu A/Mal/302/54 (H1N1)	VR-98	10^2-10^6 $CEID_{50}$/ml
Flu A/Port Chalmers/1/73 (H3N2)	VR-810	10^2-10^6 $CEID_{50}$/ml

Flu A/Hong Kong/156/97 (H5N1)	-	1.3 x 10^2 $TCID_{50}$/ml
Flu A/Vietnam/1194/04 (H5N1)	-	1.0 x 10^4 $TCID_{50}$/ml
Flu A/California/04/2009 (H1N1) swl (swine lineage)	-	5.63 x 10^4 $TCID_{50}$/ml
Flu A/Auckland/1/2009 A(H1N1) swl	-	1.0 x 10^5 $TCID_{50}$/ml
Flu A/Auckland/3/2009 A(H1N1) swl	-	1.0 x 10^5 $TCID_{50}$/ml
Flu A/Chicken/NY/117228-7/01 (H5N2)	-	1.0 x 10^4 EID_{50}/ml
Flu A/Turkey/VA/SEP-66/02 (H7N2)	-	1.0 x 10^5 EID_{50}/ml
Flu A/A/ANHUI/1/2013 (H7N9)	-	1.94 x 10^6 EID_{50}/ml
Flu B/Lee/40	VR-101	10^2-10^6 $CEID_{50}$/ml
Flu B/Brigit	VR-786	10^2-10^6 $CEID_{50}$/ml
Flu B/Russia/69	VR-790	10^2-10^6 $CEID_{50}$/ml
Flu B/Hong Kong/5/72	VR-791	10^2-10^6 $CEID_{50}$/ml
Flu B/R75	VR-789	10^2-10^6 $CEID_{50}$/ml

Although this test has been shown to detect the Flu A/California/04/2009 (H1N1) and Flu A/Anhui/1/2013 (H7N9) viruses cultured from positive human specimens, the performance characteristics of this card with human specimens infected with these two influenza viruses have not been established. The Alere BinaxNOW® Influenza A & B Card can distinguish between influenza A and B viruses, but it does not differentiate seasonal influenza A virus from influenza A 2009 H1N1 or influenza A H7N9. The ability to detect human infection with the 2009 H1N1 or H7N9 influenza virus in clinical specimens is unknown.

Analytical Specificity (Cross-Reactivity):
To determine the analytical specificity of the Alere BinaxNOW® Influenza A & B Card, 36 commensal and pathogenic microorganisms (27 bacteria, 8 viruses and 1 yeast) that may be present in the nasal cavity or nasopharynx were tested. All of the following microorganisms were negative when tested at concentrations ranging from 10^4 to 10^8 $TCID_{50}$/ml (viruses), 10^7 to 10^8 organisms/ml (bacteria) and 10^6 organisms/ml (yeast).

Bacteria	**Viruses**	**Yeast**
Acinetobacter	Adenovirus	*Candida albicans*
Bordetella pertussis	Coronavirus	
Enterococcus faecalis	Coxsackie B4	
Escherichia coli	Cytomegalovirus (CMV)	
Gardnerella vaginalis	Parainfluenza 1	
Haemophilus influenzae	Parainfluenza 2	
Klebsiella pneumoniae	Parainfluenza 3	
Lactobacillus casei	Respiratory Syncytial Virus (RSV)	
Legionella pneumophila		
Listeria monocytogenes		
Moraxella catarrhalis		
Neisseria gonorrhoeae		
Neisseria meningitidis		
Neisseria sicca		
Neisseria subflava		
Proteus vulgaris		
Pseudomonas aeruginosa		
Serratia marcescens		
Staphylococcus aureus		
Staphylococcus aureus (Cowan protein A producing strain)		
Staphylococcus epidermidis		

Bacteria	Viruses	Yeast
Streptococcus, Group A		
Streptococcus, Group B		
Streptococcus, Group C		
Streptococcus, Group F		
Streptococcus mutans		
Streptococcus pneumoniae		

Interfering Substances:
The following substances, naturally present in respiratory specimens or that may be artificially introduced into the nasal cavity or nasopharynx, were evaluated in the Alere BinaxNOW® Influenza A & B Card at the concentrations listed and were found not to affect test performance. Whole blood (1%) did not interfere with the interpretation of negative Alere BinaxNOW® Influenza A & B Card results, but did interfere with the interpretation of Flu A LOD positive samples. Therefore, visibly bloody samples may not be appropriate for use in this test.

Substance	Concentration
1 OTC mouthwash	20%
3 OTC nasal sprays	15%
3 OTC throat drops	15%
2 OTC throat sprays	20%
4-acetamidophenol	10 mg/ml
Acetylsalicylic acid	15 mg/ml
Albuterol	20 mg/ml
Chlorpheniramine	5 mg/ml
Dextromethorphan	10 mg/ml
Diphenhydramine	5 mg/ml
Guaiacol glycerol ether	20 mg/ml
Oxymetazoline	0.05%
Phenylephrine	50 mg/ml
Phenylpropanolamine	20 mg/ml
Rebetol®	500 ng/ml
Relenza®	20 mg/ml
Rimantadine	500 ng/ml
Synagis®	0.1 mg/ml
Tamiflu®	50 mg/ml

Reproducibility Study:
A blind study of the Alere BinaxNOW® Influenza A & B Card was conducted at 3 separate sites using panels of blind coded specimens containing negative, low positive, and moderate positive samples. Participants tested each sample multiple times on 3 different days. There was 97% (242/250) agreement with expected test results, with no significant differences within run (replicates tested by one operator), between run (3 different days), between sites (3 sites), or between operators (6 operators).

Signed _____ Date _____

Angela Drysdale

VP Regulatory and Clinical Affairs – Infectious Disease
Alere Scarborough, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

ALERE SCARBOROUGH INC.
ANGELA DRYSDALE
VP OF REGULATORY AND CLINICAL AFFAIRS - INFECTIOUS DISEASE
10 SOUTHGATE ROAD
SCARBOROUGH ME 04074

December 5, 2013

Re: K133411
Trade/Device Name: Alere BinaxNOW® Influenza A & B Card
Regulation Number: 21 CFR 866.3330
Regulation Name: Influenza virus serological reagents
Regulatory Class: I
Product Code: GNX
Dated: November 5, 2013
Received: November 7, 2013

Dear Ms. Drysdale:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Uwe Scherf -S for

Sally Hojvat, M.Sc., Ph.D
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K133411

Device Name: Alere BinaxNOW® Influenza A & B Card

Intended Use: The Alere BinaxNOW® Influenza A & B Card is an *in vitro* immunochromatographic assay for the qualitative detection of influenza A and B nucleoprotein antigens in nasopharyngeal (NP) swab, nasal swab, and nasal wash/aspirate specimens. It is intended to aid in the rapid differential diagnosis of influenza A and B viral infections. Negative test results are presumptive and should be confirmed by cell culture or an FDA-cleared influenza A and B molecular assay. Negative test results do not preclude influenza viral infection and should not be used as the sole basis for treatment or other patient management decisions.

***Caution**: Assay sensitivity for nasal wash/aspirate samples was determined primarily using archived specimens. Users may wish to establish the sensitivity of these specimens on fresh samples.*

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

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